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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,660	09/15/2005	Jean-Louis Junien	102717.58257US	9879

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CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,660	JUNIEN ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14-18, 20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed November 24, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 12-18, 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Obesity Research 1998) in view of Chaput et al. (Biochemical and Biophysical Research Communications 2000). This rejection is maintained.

Applicant's Arguments

Applicant argues the ditherapy comprising a combination of metfomin and fenofibrate is more effective than monotherapy of each drug alone. The ditherapy is not a simple addition of the monotherapies, but rather a synergy. One of skill in the art would not be motivated to combine the two compounds to treat obesity.

Examiner's Response

Applicant's data from Table 3 appear to demonstrate only additive effects based on the error of the values, and there also appears to be some overlap between the fenofibrate body weight and the fenofibrate plus metformin body weight, where both encompass 48 grams. In regards to Table 2, the individual values for T0 and T15 appear additive when comparing the first 4 values. It is difficult to determine if there is any synergistic effect based on the percentages because the percentages are ratios and are reflective of the numbers for T0 and T15 and not really the change in T0 and T15 values.

Declaration by Jean-Louis Junien

The declaration asserts the combination of metformin and fenofibrate significantly lower body weight gain and the results are superior to the effect of each drug alone. The combination of metformin and other acceptable salts of fenofibric acid would yield the same results. One of skill in the art would not be led to combine metformin and fenofibrate in a formulation to treat obesity. In addition one could not predict that such a particular combination would have a significant effect on body weight reduction as depicted in Table 3. The significance or relevance to combine these two compounds together is never disclosed. The combined disclosure never suggest mixing the two compounds together for the treatment of obesity and all of the references are related to various diseases or disorders without being specifically related to obesity. Other references teach each compound separately and as one of skill in the art, the Declarant asserts theses references cannot make the present invention obvious as a worker in

this field would not have any reason to presume the experimentally obtained effect on body weight reduction exhibited by the combined use of metformin and fenofibrate.

Examiner's Response to the Declaration

The Examiner disagrees and submits that the in regards to Lee et al. and Chaput et al., one of skill in the art would be motivated to combine the two compounds because they both promote weight loss in diabetic subjects. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Therefore one of skill in the art would logically combine the two components to treat obese subjects. In regards to the results in Table 3, as stated above, when comparing the results for fenofibrate and the combination of fenofibrate and metformin, it appears the two formulations have overlapping effects. The body weight gain for fenofibrate ranges from 46.2 to 57.8 and the body weight gain fro the combination ranges from 40.3 to 48.6. Therefore the two appear to have similar effects within the range of error. The addition of metformin with fenofibrate at the lowest range appears to be about the same as the formulation comprising both drugs. Therefore the combination of the two drugs appears to have an additive effect.

Additionally, claims drawn to (unexpectedly) synergistic combinations of known ingredients must be factually supported by data commensurate in scope with the claims. *See*, In re Kollman, 201 USPQ 193 (C.C.P.A. 1979). The claims are not commensurate

in scope with the results because they encompass drugs other than that disclosed by the table and the claims encompass amounts other than that disclosed by the Examples. Although the Declarant asserts that these drugs will provide the same results, there is no evidence provided to support this assertion.

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Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 12, 14-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonhomme et al. (US 6,372,790) in view of Lee et al. (Obesity Research 1998) and Chaput et al. (Biochemical and Biophysical Research Communications 2000).

Bonhomme et al. disclose a pharmaceutical composition comprising metformin; a fibrate selected from fenofibrate and bezafibrate; and optionally one or more pharmaceutically acceptable excipients for the treatment of non-insulin dependent diabetes. The weight ratio of the metformin and the fibrate ranges from 1:1 to 20:1. According to the invention, the medicinal combination is intended to refer either to a pharmaceutical composition, in which the two active principles are the essential constituents of the same composition, or to a kit comprising two separate compositions, the first comprising metformin or its pharmaceutically acceptable salt as sole active principle, and the second comprising fibrate as sole active principle (col. 4, lines 25-32), encompassing claims 16 and 17. Metformin comprises 100 to 1000mg per unit dose and fenofibrate comprises 50 to 300 mg per unit dose. Daily dosages range from 100 to

2000 mg of metformin and from 50 to 600 mg of fenofibrate (col. 4, lines 45-59), encompassing claims 14, 15, 20 and 21.

The reference differs from the instant claims insofar as it does not disclose the combination is used to treat obesity.

Lee et al. disclose metformin often promotes weight loss in patients with non-insulin-dependent diabetes mellitus by causing decreased food intake. The dosage ranged form 850 mg to 1700 mg. The reference differs from the instant claims insofar as it does not disclose treating obesity with a PPAR alpha agonist.

Chaput et al. disclose fenofibrate decreases body weight in fatty Zucker rats. The fibrate compounds improve lipidic control (paragraph 0015). The reference differs from the instant claims insofar as it does not disclose metformin is used in combination with fibric acid derivatives to treat obesity.

Non-insulin dependent diabetes is usually associated with obesity. It would have been obvious to one of ordinary skill in the art to have used the compositions of Bonhomme et al. to treat obesity motivated by the desire to use a composition that treats diabetes as well as comprise metfomin and fenofibrate which have been disclosed in the art to promote weight loss.

Claims 12, 14-18, 20 and 21 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612